AMENDMENT TO RULES COMMITTEE PRINT 117-31

OFFERED BY M__. _____

On page 1520, at the end of line 22, insert the following:

TITLE XI—COUNTERFEIT MEDICAL PRODUCTS

SEC. 61101. COUNTERFEIT MEDICAL PRODUCTS.

(a) FINDINGS.—Congress finds the following:

(1) Medical products, as defined by Food and Drug Administration (FDA) statute to mean a drug, biological product, device, medical food, or infant formula, are often produced and shipped to the United States from abroad. As noted in 2019 testimony by investigative journalist Katherine Eban before the U.S.-China Economic and Security Review Commission, ''The U.S. drug supply is 90 percent generic, with a majority of those drugs coming from overseas, principally India and China. As well, 80 percent of the active ingredients in all our drugs, whether brand or generic, come from overseas, the bulk of those from China and India.''.

(2) Some of these imports are counterfeit, adulterated, and intentionally misbranded medical products that are designed to mislead the consumer, including patients and health care providers, as to the safety and soundness of the medical products for sale.

(3) The Organisation for Economic Cooperation and Development (OECD) estimated in 2016 that the global trade in counterfeit drugs alone is $4.4 billion, which does not include losses to the legitimate industry.

(4) In 2013, the World Health Organization (WHO) estimated that between 10 and 30 percent of drugs sold worldwide are substandard or falsified, including cancer, diabetes, and anxiety drugs. It also projected that one million people a year die as a result.

(5) Additionally, the rise in online pharmacies and shopping has also coincided with a rise in illegally marketed and unapproved medical products targeted to United States consumers.

(6) The WHO estimates that up to 50 percent of illicit online pharmacies are selling counterfeit medical products. Directed towards United States consumers, these illegitimate online sellers advertise

themselves as Canadian-based pharmaceutical companies to reassure buyers but are often front companies for are counterfeit, adulterated, and intentionally misbranded medical products produced in China and India.

(7) Since 2008, FDA has partnered annually with Homeland Security Investigations and international regulatory and law enforcement agencies on ''Operation Pangea'' to target websites engaged in the online sales and smuggling of potentially dangerous, unapproved versions of opioid, oncology, and antiviral prescription drugs and other medical devices into the United States.

(8) During the deadly, global pandemic caused by COVID–19, the FDA has seen a dramatic increase in the number of tainted medical products that have been sent to the United States. For example:

(A) The U.S. Customs and Border Protection (CBP) has reported that at the height of the pandemic, during the first three months of 2021, it seized 18 million counterfeit respirators (more commonly known as face masks), compared to only 1,300 counterfeit respirators seized in fiscal year 2019.

(B) As of September 2020, the Food and Drug Administration had refused admission to more than 470 shipments of test kits at the border, representing more than 460,000 tests overall.

(C) As of June 1, 2020, CBP had seized more than 107,300 unauthorized COVID–19 test kits.

(9) The COVID–19 pandemic also contributed to an increase in online sales and smuggling of illicit medical products. In 2021, ''Operation Pangea XIV'' resulted in seizures of illicit medical products with an estimated value of around $23,414,483. In addition, 113,020 websites were removed, the highest number since the first ''Operation Pangea'' in 2008.

(10) While there are laws that govern the penalties for manufacturing and selling these fraudulent medical products, there are clearly instances of sustained effort by bad actors to avoid United States laws and regulations to manufacture and sell counterfeit, adulterated, and intentionally misbranded medical products that harm public health and safety.

(11) Particularly in the context of the COVID–19 pandemic, this ''pattern or practice'' by certain

bad actors of intentionally and consistently misleading consumers and the healthcare industry as to the safety and legitimacy of medical products raises these instances to the level of a national security concern.

(12) The Office of Foreign Assets Control (OFAC) administers and enforces economic and trade sanctions in support of United States national security and foreign policy objectives. Existing sanctions programs authorize OFAC to target persons engaged in human rights abuses, transnational organized crime, and cyber fraud. OFAC does not currently have a sanctions regime explicitly targeted at persons engaged in a pattern or practice of intentionally producing and selling counterfeit, adulterated, and misbranded medical products to United States consumers, but some of its regimes might be appropriately applied to address this national security concern.

(b) IN GENERAL.—It is the sense of Congress that the proliferation of counterfeit, adulterated, misbranded or unapproved medical products from Chinese and other foreign manufacturers and exporters poses a public health and safety risk that reaches the level of a national security concern.

(c) USE OF EXISTING SANCTIONS AUTHORITY.—The Secretary of the Treasury shall direct the Office of Foreign Assets Control, in coordination with the Commissioner of the Food and Drug Administration, to, when necessary for public health or national security as determined by the Office of Foreign Assets Control, use the existing sanctions authorities of the Office of Foreign Assets Control for persons found by the Commissioner of the Food and Drug Administration under the Federal Food Drug and Cosmetic Act to be engaged in a ″pattern or practice of producing or distributing counterfeit, adulterated, misbranded or unapproved medical products with the intent to defraud or mislead the consumer.

(d) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary of the Treasury, acting through Office of Foreign Assets Control shall submit to House Committees on Financial Services and Energy and Commerce and the Senate Committees on Foreign Relations, Health, Education Labor and Pensions, and Banking, Housing, and Urban Affairs, a report that addresses whether existing sanctions authorities of the Office of Foreign Assets Control are sufficient to address the production and distribution of counterfeit, adulterated, misbranded or unapproved medical products that meet the requirements of subsection (c).

(e) DEFINITIONS.—In this section:

(1) MEDICAL PRODUCT.—The term ''medical product'' means a drug, biological product, device, medical food, or infant formula.

(2) BIOLOGICAL PRODUCT.—The term ''biological product'' has the meaning given the term in section 351 of the Public Health Service Act.

(3) MEDICAL FOOD.—The term ''medical food'' has the meaning given the term in section 5 of the Orphan Drug Act.

(4) ADULTERATED MEDICAL PRODUCT.—The term adulterated medical product means an adulterated drug or adulterated device as such terms are described in section 501 of the Federal Food, Drug, and Cosmetic Act.

(5) MISBRANDED MEDICAL PRODUCT.—The term ''misbranded medical product'' means drug or device that has been misbranded as described in section 502 of the Federal Food, Drug, and Cosmetic Act.

(6) COUNTERFEIT MEDICAL PRODUCT.—The term ''counterfeit medical product'' means a counterfeit drug and a counterfeit device.

(7) ADDITIONAL TERMS.—The terms ''device'', ''drug'', ''infant formula'', and ''labeling'', ''counter-

feit drug'', ''counterfeit device'' have the meaning given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act.